HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4768

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-05

October 28, 1999

Carlos J. Meza
President
Ancar Import Corporation
1375 N.W. 89th Court, Bay #6
Miami, Florida 33172

Dear Mr. Meza:

On August 5, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 1375 N.W. 89th Court, Bay #6, Miami, Florida 33172. The investigator, Maria A. Medina, documented a serious deviation from the seafood importing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). This violation causes the fish products being imported and stored by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

> Your firm has failed to list and implement written product specifications designed to ensure that the seafood products are not adulterated, as required in 21 CFR § 123.12(a)(2)(i)].

The above identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256), Miami, Florida 33159-2256.

Sincerely,

Edward R. Atkins for

Douglas D. Tolen
Director, Florida District

bcc:
HFR-SE240/KWH/ LGL JKT/WL FILE
HFR-SE250/MAC/EI JKT
MIA-RP
HFA-224
HFI-35 (PURGED)
HFC-210
HFS-606

DR. FRUIN, W/483
CHIEF, BUREAU OF FOOD & MEAT INSPECTION
FDACS/DIVISION OF FOOD SAFETY
3125 CONNER BLVD.
TALLAHASSEE, FL 32399-1650

approved by HFS-606 ON 4/19/99 with request for update inspection.

f/u insp: 8/5/99

WL final: 10/28/99